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Commercialization of Biobank Data:

The Case Auria Biobank

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ABSTRACT

This study presents a case of commercialization in an emerging business field. The subject of study is Auria Biobank, the leading clinical biobank in Finland. The study depicts the development of the case organization and examines how the biobank seeks to establish business operations around its depository of tissue samples and patient records. This case study examines emerging of commercial activity associated with personalized medicine from the perspective of a biobank. The results of the study will present an evaluation of the challenges and opportunities a biobank faces when developing operations to utilize digitalized biobank data for commercial research and development (R&D) purposes.

Keywords: Biobanks, Commercialization, Innovation, Challenges, Opportunities

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INTRODUCTION

Biobanks are considered as central actors in the future health care envisioned to be ‘personalized, predictive, preventive, and participatory’ (Hood & Friend, 2011). In the context of ’personalized medicine’, which the new paradigm of health care is usually called (e.g. Tutton, 2014), combination of data from tissues samples, clinical data, and personal health records in a digital form is expected to provide more effective means for

curing and preventing diseases, and for reducing the costs of health care. The term 'biobank' refers to a variety of social and technical arrangements for the collection, storage, and exchange of biological materials and associated medical and life style information. They collect, store and circulate data which is vital for biomedical research, and therefore biobanks are becoming a key infrastructure for biomedicine. (Yuille, 2011; Yuille et al., 2008.) The operations of biobanks are still in early development, but there are great expectations for the field to advance and contribute to the development of personalized medicine.

This case study examines the progress in personalized medicine from the perspective of a biobank based in Finland. In the global perspective, Finland is one of the most advanced countries in biobanking with extensive collections of tissue samples, well organized and easily accessible health data in hospital medical records, public health registers and longitudinal epidemiological studies, and proper legal and administrative regulatory framework for biobanking. In the national scene, our case Auria Biobank is in many ways a pioneer.

OBJECTIVES

The subject of our case study is Auria Biobank, which is the first clinical biobank in Finland. The study depicts the development of the case organization and examines how the biobank seeks to establish business operations around its depository of tissue samples and patient records. The interest in this study is in examining how Auria biobank engages in commercialization activity in an emerging business field. Our purpose is to examine the challenges and opportunities a biobank faces when developing operations so that digitalized biobank data can be utilized for commercial research and development (R&D) purposes. In addition, we study what kind of threats and bottlenecks emerge in commercialization of biobank activities.

THEORETICAL BACKGROUND

Commercialization of innovation has become a focal topic in business studies over the past decade. Bringing a new product or service to the market is challenging in any field of business, but it is particularly challenging in the field of medicine, where it may take years to create a successful business based on an innovation. The traditional understanding of commercialization of innovation builds on a goods dominant logic of value creation (GDL) (Vargo & Lusch 2004, Vargo & Lusch, 2008). The GDL builds on an ideal of a linear innovation process in which, first, researchers, a research organization or a firm engages in creating ideas and inventions, and then seeks to find customers who would be interested in buying the innovation created by the innovator. This line of thinking builds on an assumption of value exchange in which the customer receives a product or a service and makes a payment in return. The relationship between the innovator and the customer is that of exchange of value, and the attention is focused on the process of creating an innovation, making a product or a service, and the price that a customer is willing to pay for the innovation. The primary attention in GDL in innovation management is in the value creation opportunities of the innovator.

Another understanding of commercialization of innovation is the service dominant logic (SDL), which seeks to understand better how customer value is created and what is the value in use for the customer (Vargo & Lusch, 2004; 2008; Lusch & Vargo 2006; Vargo, Maglio, & Akaka, 2008). In this approach to innovation, the company with an innovative offering creates a value proposal with the product or service, and the final value is created in collaboration with the customer. This approach calls for interaction and trust between the company and the customer since very early stages of innovation as the customer is treated as a co-creator of value. The underlying idea is that both the producer of the product or service and the customer create value together with the new solution. This approach highlights innovation and value creation as synchronic and interactive processes instead of treating them as linear and transitive processes. This approach to commercialization of innovation calls for reconsidering the roles, actions, and interactions among economic actors (Ramirez, 1999). SDL calls for creating collaborative business arrangements and makes seeking to establish longer term relationships between customers and producers as viable and important. An ability to co-operate and create value together is considered to be the primary source of competitive advantage that commercialization of innovations creates.

METHODOLOGY

This study is an intensive case study. This approach enables the use of rich details of one case organization and allows producing a narrative interpretation about the case from the perspective of the people involved in the case (Eriksson & Kovalainen, 2016, 134-135). Furthermore, this approach allows for capturing in detail the social and material processes involved in medical innovation (Nicolini, 2010). Two of the authors have engaged in dialogue with the company for a period of two years. They have held regular meetings in the company. The data used in this study comprise minutes from the meetings, two recorded and transcribed interviews, and company material. The first interview was with the CEO of Auria in November 2013 (HSM 2013), and the second interview was with the CEO of Auria in February 2016 (HSM 2016).

Also, news articles and other publicly available material on the development of biobanks and personalized medicine have been used as data in this study. Content analysis was used as a method of analysis (Eriksson & Kovalainen, 2016).

THE CASE STUDY

Auria Biobank is a clinical biobank closely linked with the Turku University Hospital. The city of Turku is located in Southern Finland, and it has a history of the original university town in Finland. Currently, Turku is focusing on investing in health technology innovation and business ecosystem in the area. Auria Biobank was founded in 2012 by the University of Turku and three hospital districts, and it was registered as a biobank by the National Supervisory Authority for Welfare and Health in March 2014. Auria is one of the eight biobanks in Finland. It was the first clinical biobank in Finland and, today, it is the only biobank that is actively supplying its data outside research institutions and pursue for collaboration and commercial activity. The other five clinical biobanks in Finland are preparing or in very early stages in arranging their sample collections and data depositories. In addition to six clinical biobanks, there are a population based, epidemiological biobank run by the National Institute for Health and Welfare, and a biobank focused on blood diseases in Finland, at the moment. All biobanks in Finland have to undergo a registration process as defined in the 2013 Biobank Act (§688/2012).

The core of Auria biobank is the depository of medical data, which consists of biological samples (blood, urine, biopsy samples etc.), related bioinformation like DNA sequences, and patient data from the hospital clinics. The biobank maintains and extends its depository, and delivers data to appropriate medical research projects and partners, both public and private. Auria's objective is to 'capture all incomers' which means getting new samples from every patient enrolled in the district's hospitals. This collection of new samples started in spring 2015. Most of Auria's samples are, however, old diagnostic samples transferred from the hospital collections to the biobank. During the first two years of its operation, Auria has managed to extend its collection to about one million samples from which the biggest group is cancer related samples. Auria is engaged with some 40 research projects. Of them, 63% are academic, and 37% with private pharmaceutical and other medical enterprises (Auria webpage), including pharmaceutical giants Bayer, Roche and Novartis.

FINDINGS

Auria Biobank is a public and academic institution, and its main purpose is to advance Finnish biomedical research. Auria collaborates closely with universities and research centers. It is also involved in developing commercial activity from biobanking. The key actors in Auria reason that business activities and profitable collaboration with private enterprises and the Big Pharma corporations are an important way, if not a necessity, in sustaining and developing biobanking activities. This is reflected in the comment by a director of Auria:

> *"At least a half of the annual expenses of the biobank should be covered by our own funding received from business collaboration with private enterprises." (HSM 2016).*

For Auria, biobanking business is explicitly instrumental. This means that seeking commercial success and profits are meant to serve the maintenance of the crucial biomedical infrastructure and the development of better medical treatment. Despite of this emphasis, a great deal of activities in Auria are focused on dealing with commercial collaboration and marketing biobank services. Thus, the *commercialization* of biobank data and the relevant aspects of data management in a manner that would make Auria competitive in medical research business has become a key task of biobanking. This emphasis has emerged from a two-year experience of operating as an actual biobank, during which time *"biobanking has appeared to be in many ways different from what we expected when founding it"* (HSM 2016).

What makes Auria competitive and capable of doing successful business, then? According to the key person interviews and public documents, Auria considers that becoming 'attractive' for private enterprises as a partner and also as a target of private investments is the core of the biobank business. In this context, collaboration means R&D activities with partners and investors. Furthermore, a biobank becomes attractive if it has something 'unique' to offer to a partner or an investor as regards to their medical R&D activities. According to their own evaluation, the uniqueness of Auria Biobank as compared to the competitors – i.e. biobanks around the globe – consists of several factors. First, Finland is considered to offer an environment for biomedical R&D not to be found anywhere else in the world, and Auria is the leading biobank in Finland. The main assets of Finland are public health care system which maintains comprehensive patient records and medical and population registers in an electronic and easily accessible form, extensive collections of tissue samples in the Finnish biobanks, high expertise in biomedical research and biobanking, people who are willing to donate samples and personal data for research, and popular trust towards biomedical researchers and public authorities. This view is similar to those presented in documents of innovation policy attached to medical genomics and personalized medicine in Finland (TEM 2014; STM 2015; see also Soini 2013).

Second, Auria considers data in its collections as its main asset in global biobank business:

> *"An essential potential for creation of value in Finnish biobanks is considered to be research data acquired by combining human tissue samples with information from electronic health records. In addition, Finland has an advanced institutional environment for carrying out such combination of samples and health record data." (Selvitystyö 2016)*

Auria's collection of approximately million data units (at the moment) is unique because Auria can combine biological information (like DNA sequences) received from tissue samples with clinical data of the hospital patient records. According to Auria actors' experiences of collaboration with pharmaceutical and other medical companies, Auria is seen as an attractive partner particular due to the clinical data which the biobank provides in a standard and accessible form and combined with precise biological data:

> *"(…) so an interested researcher can see from our metadata how many breast cancer cases [with tissue samples] we have, and what ages, and what lab values attached, and what other ICD-10 diagnoses, and hormone statues, and other available information (…)" (HSM 2013).*

Such 'real life data' are seen to be of great help in targeting biomedical research of drugs or diagnostic biomarkers, and for that reason Auria's data are 'attractive':

> *"They are particularly interested in our phenotype data (…) it is precisely the clinical data of our hospital patients which allows deep phenotyping, so that we can find exactly the right patient for the right study." (HSM 2016)*

Thus, the main commercial asset of Auria biobank is embedded in and dependent on the systematic and advanced Finnish public health care system and public record keeping.

However, Auria thinks that its competitive advantage lies not merely in its data collections *per se* but in its expertise in management of such data. Pharmaceutical and other medical companies are believed to be interested in datasets combined from sample collections, patient records, and national health care and

population registers. Auria is very potent to meet this demand, because it has developed advanced practices of data management which combine sample management, bioinformatics and administrative expertise for making up required data. With the help of its expertise and experience in biobank data management, Auria can provide tailor-made and co-designed data from its depository to commercial partners. On the basis of interviews and documents, Auria seems to consider that the provision of a wide variety of flexible data management services for medical R&D is and will be the core of the biobank business activity and collaboration with private enterprises. This view is reflected in Auria's public image as it lists, among others, real life data analyses, consultation, feasibility studies, and tissue microarray in its services portfolio (Auria webpage). However, key actors of Auria think that their competitiveness will condense in one issue:

> *"What pharmaceutical companies might be very interested is our potential to identify patients for clinical drug studies. (…) I think that this stratification of research patients almost the only thing that we can compete [in pharmaceutical trials with India or China]." (HSM 2013)*

Auria's key actors think that, despite of being a way ahead of other clinical biobanks in Finland, Auria is still in early developing phase in its activities, especially regarding commercial collaboration. In this situation, Auria biobank needs to change and develop in order to sustain biobanking successfully in the future. The key actors emphasize that a major direction of change in business mode is to move ahead from single collaborative projects to 'strategic partnership' with big medical corporations. In concrete terms, this would mean longstanding contracts in R&D collaboration with Auria and medical corporations and investment in research facilities associated with Auria by big corporations or venture capital investors. Auria thinks that there are some prerequisites for this next step in biobank business.

The most vital change which Auria repeats time and again is extending biobank sample and data depositories into a nationwide collection or linking the collections of the Finnish biobanks under a national biobank organization. This is also the main objective of the Finnish biobank policy and 'genome strategy' (STM 2015). Such a national concentration is expected to make Auria and other Finnish biobanks more competitive in the global medical R&D business in two ways. First, uniting or linking depositories of the Finnish biobanks, especially clinical biobanks, would multiply the available biological and clinical data, and the mere extension of databases is thought to make Finnish biobanks more 'attractive' to commercial partners. In addition, a single national biobank center would provide the potential partners a simple and flexible access to extensive yet manageable databases and data management services of Auria and other Finnish biobanks.

In order to take the step towards a 'strategic partnership' with medical enterprises, Auria needs also to adopt an organization form compatible with business collaboration. At the moment, Auria is administered as a public institution in the framework of public bureaucracy which is far from an ideal for running and extending business activities of the biobank. Parallel with on-going association process of biobanks, Auria has started to change its organizational and legal form. A major challenge in this change is matching Auria's essentially public character with commercial activities. Interestingly, the biobank seems to be moving toward a co-operative company organization (Selvitystyö, 2016).

DISCUSSION

Our analysis depicts Auria Biobank as a public and academic institution that seeks to be engaged with commercial R&D activities and alliances with pharmaceutical and other medical corporations in order to sustain its capacity to maintain and extend the data depository for biomedical research. Auria is operating in many ways in-between research and business, performing so-called 'third stream' activities (Shore & McLauchlan, 2012) with a focus on the commercialization of science. Today, it is typical of public research institutes to engage with the third stream activities which tendency is engendered by an idea of 'relevance' that publicly funded science should have for society. In this context, economic aspects of social 'relevance' are emphasized, and they serve as a basis and justification for business activities and partnerships of academic institutions like Auria. Such pursue for business is associated with an idea that the revenues could be directed back to science.

Within this framework, Auria's business model of biobanking seems to include elements of both mentioned rationales of commercialization of innovations. The view that the main asset of Auria in global medical R&D business is the 'unique' Finnish biological and medical data in its depository fits in well with the goods dominant logic of value creation (GDL). From this perspective, Auria is doing business by selling combinations of biological data from its tissue samples and clinical data from its patients' records to medical companies which see a particular value in those datasets for their testing of new drugs or diagnostic methods. However, Auria sees more prospects for commercialization in data management services associated with making combinations of biological and clinical data. Its rationale as regards to data management services is in line with the service dominant logic of value creation (SDL). Auria is aiming at not only selling biobank services to medical companies but building up partnerships in medical R&D which would benefit involved parties in their commercial activities. Auria considers pharmaceutical and other medical companies as their primary partners in co-creation of medical innovations and value; however, they envision that other Finnish biobanks, Finnish start-up companies in biomedicine and bioinformatics, health care institutions, and even patients and publics as sample and data donors are potentially included in the sphere of partners in creation of innovation and value. In any case, from both the GDL and the SDL perspective, the commercial value – or, rather, value potential – of Auria Biobank is particularly embodied in *clinical data*, not so much in tissue samples.

It is notable that values and value potential of Auria Biobank's business activities and partnerships are promissory and embedded in prospects and expectations. This is typical for commercial environments of emerging sciences and technologies like biotechnology and biomedicine, in which business models and opportunities are wrapped by interrelated promises (e.g. Parandian, Rip, & Te Kulve, 2012). The promise of value is manifold. First, Auria is marketing to medical corporations a promise that its data and data management service would add value to the prospects a partner has regarding drug development or other medical R&D. Second, Auria's model to sustain the biobank is based on prospects of future commercial collaboration with Big Pharma and other medical companies. In Auria's view this commercialization of biobanking also justifies the demands for public funding. Thus, from a business perspective, Auria biobank is concentrated on working upon expectations and promissory values by maintaining and extending its collections of biological and clinical data and data management service portfolio.

CONCLUSION

This study has introduced Auria Biobank as a pioneer in the future medicine in Finland and examined how it seeks to commercialize its assets related to bioinformation. Commercialization strategies indicate how the organization aims to compete and co-operate, with whom, when and how (Gans & Stern, 2003). This contributes to literature on commercialization by showing how a science based company in an emerging business field draws on both goods dominant logic and service dominant logic in commercialization. Furthermore, this study shows that commercialization involves both planned and emergent commercialization strategies when seeking to create value for customers.

This case study shows that while Finnish biobanks have unique characteristics compared to biobanks in other countries, they have a good basis for reputation based commercialization strategies, in particular. The commercialization strategy of Auria Biobank is very much focused on customer value, and it is utilizes both close collaboration with customers and arms-length selling to customers. A broad use of commercialization strategies can be seen as a strength in creating a viable business in the future. To continue this case study, a more detailed analysis of the social and material networks will be conducted. The network analysis is expected to provide a deeper understanding of the dynamics of commercialization and business development.

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